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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,946	04/20/2001	Rebecca E. Cahoon	BB1410PCT	9292
27310 7590 04/09/2007 PIONEER HI-BRED INTERNATIONAL, INC. 7250 N.W. 62ND AVENUE P.O. BOX 552 JOHNSTON, IA 50131-0552			EXAMINER BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

09/807,946

Applicant(s)

CAHOON ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 6-15, 19-29 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 6-15, 19-29, 36-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The amendment filed 1/18/2007 has been entered.
2. Claims 1, 3-4, 6-15, 19-29 and 36-41 are pending.  
Claims 2, 5, 16-18 and 30-35 have been canceled.  
Claims 36-41 have been newly added and are drawn to the elected invention.
3. Claims 1, 3-4, 6-15, 19-29, 36-41 including SEQ ID NO:5, 6, 7 and 8 are examined in the present office action.
4. Rejections and objections not set forth below are withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### ***Indefiniteness***

6. Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 remains rejected and claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Applicant does not recite an expression. The preamble and last method step are not congruent. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/19/2001. Applicant's arguments filed 1/18/2007 have been fully considered but they are not persuasive.

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Applicants contend claims 9 and 10 are drawn to "functional RNA", and therefore an expression step is not essential to the claimed method (page 18 of Remarks, top paragraph).

The Office contends the recitation "functional RNA" does not obviate the rejection. It is not clear what is the function of the RNA in relation to modulating the level of WUS protein. For example, is the RNA part of the translation process so that an increase of WUS protein ensues or is the RNA acting to inhibit gene expression, for example, by an antisense mechanism? Given the ambiguity of "functional RNA" as it pertains to claims 9 and 10, claims 9 and 10 do not further define "functional RNA" or do not indicate how the "functional RNA" is used for the purpose of modulating the level of WUS protein.

#### *Written Description*

7. Claims 1, 5-15 and 19-29 remain rejected and new claims 36-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/19/2001. Applicant's arguments filed 1/18/2007 have been fully considered but they are not persuasive.

Applicants contend that twelve Wuschel cDNAs from corn or soybean and known Wuschel polypeptide from Arabidopsis are described (page 19 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend they further describe the genus of polynucleotides and encoded polypeptides structurally using percent sequence identity, which describes features common to the members of

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the genus (*Ibid*). Applicants contend an alignment of sequences in Figure 1 is supplied which illustrates regions of amino acid conservation and in Appendix B an additional alignment of all the polypeptides disclosed is presented (*Ibid*).

The Office acknowledges receipt of the alignment in Appendix B, but based on a later filed application (i.e., 10/744,572) which claims priority to the present application, there are two Wuschel genes in corn (see paragraph bridging pages 6 and 7 of '572 application). In addition, the state-of-the-art teaches that not all WUS genes have the same function. Nardmann et al (2006, Mol. Biol. Evol. 23(12):2492-2504) teach maize has two WUS genes, WUS1 and WUS2, which have a different expression pattern as compared to WUS from Arabidopsis (paragraph bridging pages 2494-2495). Nardmann et al state "The expression patterns of WUS orthologues in both grass species compared with those of dicots imply that major changes in WUS function, which are correlated with changes in CLV1 signaling, have occurred during angiosperm evolution and raise doubts about the uniqueness of the WUS/CLV antagonism in the maintenance of the shoot stem cell niche in grasses" (abstract). Nardmann et al also disclose that ZmWUS1 and ZmWUS2 have different expression patterns which reflects their different functions (paragraph bridging pages 2496-2497; page 2500, right column, bottom paragraph and page 2501, left column). Therefore, it is not clear from applicants' alignment which of the Wuschel genes are being aligned. In addition, given the teaching of Nardmann et al, monocot and dicot Wuschel genes have different functions and therefore the alignment comprises orthologues with different functions, which is not an accurate representation of the claimed genus.

***Enablement***

8. Claims 1, 5-15 and 19-29 remain rejected and new claims 36-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/19/2001. Applicant's arguments filed 1/18/2007 have been fully considered but they are not persuasive.

Applicants contend the presence of working examples is not the standard for enablement (page 20 of remarks, 2<sup>nd</sup> full paragraph). Applicants contend that twelve sequences were described structurally and illustrated by alignment in Figure 1 as discussed above, and Applicants disclose that "five novel Wuschel sequences aligned with Arabidopsis Wuschel" (page 20 of Remarks, 2<sup>nd</sup> full paragraph). Applicants contend the specification discloses the isolation, identification and characterization of clones from corn and soybean and stable and/or transient transformation (*Ibid*). Applicants state "Enablement at the time of filing is further illustrated in Appendix C, which summarizes experimental data generated using two Wuschel sequences, and sequence identity comparisons of the sequences transformed into plants as compared to the sequences under examination in the instant application" (page 20 of Remarks, 2<sup>nd</sup> full paragraph).

The Office contends that Applicants have not transformed a plant with a nucleic acid encoding a polypeptide comprising at least 100 amino acids, wherein the amino acid sequence of the polypeptide has at least 80% identity to SEQ ID NO:6 or 8 based on the Clustal alignment method. The Federal Circuit has repeatedly held that "the specification must teach those skilled

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in the art how to make and use the full scope of the claimed invention without 'undue experimentation'" (See MPEP 2164.08). The Office contends Applicants have not provided guidance for one of skill in the art to identify and isolate a nucleic acid encoding a polypeptide comprising 100 amino acids and exhibiting 80% sequence identity to SEQ ID NO:6 or 8 that can be used in Applicants' invention. Applicants have only transformed corn plants with a nucleic acid encoding the WUS1 or WUS2 polypeptide, which Applicants have not identified by sequence identifier. In addition, Applicants have not indicated the relationship between all the sequences disclosed in any of the appendices. Given the state-of-the-art and unpredictability as discussed in the office action mailed 10/18/2006, given the lack of teachings by way of disclosure or example and given the breadth of the claims, undue trial and error experimentation would be required by one of skill in the art to practice the broadly claimed invention.

9. Claims 1, 3-15 and 20-29 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:5 encoding SEQ ID NO:6 or an isolated polynucleotide of SEQ ID NO:7 encoding SEQ ID NO:8, a method for transiently modulating the level of WUS protein in a plant cell, a method for inducing meristem proliferation in a plant cell and method for positive selection of a transformed cell comprising said polynucleotide, or plant, plant cell or plant seed comprising said isolated polynucleotide.

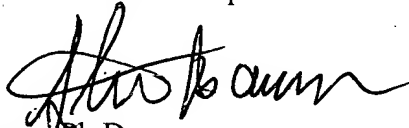
10. No claims are allowed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.

Primary Examiner

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March 28, 2007

STUART F BAUM, PH.D.  
PRIMARY EXAMINER